The following corrections or additions to the January 1999 list were published in the Federal Register in September 1999

New Approvals

NADA Number: 140-339

Note: This NADA provides for the combined use of two previously approved Type A Medicated Articles in the manufacture of Type C medicated feeds.

Trade Name:	Nicarb®, Flavomycin®
Ingredients:	Nicarbazin, bambermycins
Sponsor:	Hoechst Roussel Vet
Approval Date:	August 6, 1999
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feed.
Concentration:	Nicarbazin: 113.5 grams per pound Type A Medicated Article; Bambermycins: 2, 4, or 10 grams per pound Type A Medicated Article.
Indications:	As an aid in preventing outbreaks of cecal coccidiosis caused by *Eimeria tenella*, intestinal coccidiosis caused by *E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*, increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.445: Nicarbazin: A tolerance in uncooked chicken muscle, liver, skin, and kidney has been established at 4.0 ppm for residues. Bambermycins: No tolerance required.
Withdrawal:	4 days

21CFR 558.95 and *558.366*

NADA Number: 141-114

Note: This NADA provides for the combined use of two previously approved Type A Medicated Articles in the manufacture of Type C medicated feeds.

Trade Name:	Aviax™, Stafac®
Ingredients:	Semduramicin, virginiamycin
Sponsor:	Pfizer, Inc.
Approval Date:	July 27, 1999
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feed.
Concentration:	Semduramicin: 22.7 grams per pound Type A Medicated Article; Virginiamycin: 20 or 227 grams per pound Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/E. mitis*; increased rate of weight gain and improved feed efficiency; and prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.
Tolerance:	21CFR 556.597: Semduramicin: Tolerances are established for residues of parent semduramicin in uncooked edible tissues of 400 ppb in liver and 130 ppb in muscle. The ADI for total residues is 180 micrograms per kilogram of body weight per day. 21CFR 556.750: Virginiamycin: No tolerance required. The ADI for total residues is 250 micrograms per kilogram of body weight per day.
Withdrawal:	Zero days

21CFR 558.555, 558.635, 556.597 and *556.750*

NADA Number: 141-129

Note: This NADA provides for the combined use of two previously approved Type A Medicated Articles in the manufacture of Type C medicated feeds.

Trade Name:	Avatec®, Flavomycin®
Ingredients:	Lasalocid, bambermycins
Sponsor:	Hoechst Roussel Vet
Approval Date:	August 6, 1999
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feed.
Concentration:	Lasalocid: 90.7 grams per pound Type A Medicated Article; Bambermycins: 2, 4, or 10 grams per pound Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.347: Lasalocid: A tolerance of 1.2 ppm in skin with adhering fat has been established for chickens. Bambermycins: No tolerance required
Withdrawal:	Zero days

21CFR 558.95, 558.311, and *556.347*

NADA Number: 141-150

Note: This NADA provides for the combined use of two previously approved Type A Medicated Articles in the manufacture of Type C medicated feeds.

Trade Name:	Avatec®, Stafac®
Ingredients:	Lasalocid, virginiamycin
Sponsor:	Roche Vitamins, Inc.
Approval Date:	August 6, 1999
Status:	Over-the-counter
Route:	Oral
Species:	Growing turkeys
Drug Form:	Type A Medicated Articles to make Type C medicated feed.
Concentration:	Lasalocid: 90.7 grams per pound Type A Medicated Article; Virginiamycin: 20 or 227 grams per pound Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides,* increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.347: Lasalocid: A tolerance of 0.4 ppm has been established for residues of unchanged lasalocid in turkey liver and skin with adhering fat. Virginiamycin: No tolerance required.
Withdrawal:	Zero days

21CFR 558.311

Supplemental Approvals

NADA Number: 110-315

This supplemental application provides for the addition of tylosin tartrate to the product .

Trade Names:	1) Component® E-S with Tylan® 2) Component® E-C with Tylan®
Ingredients:	Progesterone, estradiol benzoate, tylosin tartrate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	July 20, 1999
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle
Drug Form:	Implant
Concentrations:	1) Each implant is made up of nine pellets. Eight pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate. 2) Each implant is made up of five pellets. Four pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate and one pellet containing 29 mg tylosin tartrate.
Indications:	1) For increased rate of weight gain and improved feed efficiency in steers weighing 400 lbs or more. 2) For increased rate of weight gain in suckling beef calves up to 400 lbs of body weight.
Tolerance:	21CFR 556.240: Estradiol and related esters: No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated heifers, steers, and calves (uncooked edible tissues): 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver. 21 CFR 556.540: Progesterone: No residues of progesterone are permitted in excess of the following increments above the concentrations of progesterone naturally present in steers and calves (uncooked edible tissues): 3 parts per billion for muscle, 12 parts per billion for fat, 9 parts per billion for kidney, and 6 parts per billion for liver. 21CFR 556.740: Tylosin: Tolerances are established for residues of tylosin in edible products of cattle as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Exclusivity:	3 years

21CFR 522.1940 and *510.600*

NADA Number: 140-441

This supplemental application provides for an additional tablet size of 136 mg.

Trade Name :	Baytril® Taste Tabs™ Antibacterial Tablets
Ingredients:	Enrofloxacin
Sponsor:	Bayer Corp., Agriculture Division, Animal Health Division
Approval Date:	August 3, 1999
Status:	Prescription Only
Route:	Oral
Species:	Dogs, cats
Drug Form:	Tablet
Concentration:	22.7, 68 and 136 mg per tablet
Indications:	For the management of diseases in dogs and cats associated with bacteria susceptible to enrofloxacin.

21CFR 520.812

NADA Number: 135-906

This supplemental application provides for the addition of tylosin tartrate as a local antibiotic for injection site infections.

Trade Name:	Component® E-H with Tylan®
Ingredients:	Testosterone propionate, estradiol benzoate, tylosin tartrate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	July 20, 1999
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle
Drug Form:	Implant
Concentration:	Each implant is made up of nine pellets. Eight pellets, each containing 25 mg testosterone propionate and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate.
Indications:	For growth promotion and improved feed efficiency in heifers to be used as beef weighing 400 lbs or more.
Tolerance:	21CFR 556.240: Estradiol and related esters: No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated heifers: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver. 21 CFR 556.710: Testosterone propionate: No residues of testosterone, resulting from the use of testosterone propionate, are permitted in uncooked edible tissues of heifers in excess of the following increments above the concentrations of testosterone naturally present in untreated cattle: 0.64 part per billion in muscle, 2.6 parts per billion in fat, 1.9 parts per billion in kidney, and 1.3 parts per billion in liver. 21CFR 556.740: Tylosin: Tolerances are established for residues of tylosin in edible products of cattle as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Exclusivity:	3 years

21CFR 522.842

NADA Number: 140-927

This supplemental application provides for use in a new species as an aid for improving spawning in finned fish broodstock.

Trade Name:	Chorulon®
Ingredients:	Chorionic gonadotropin
Sponsor:	Intervet, Inc.
Approval Date:	August 6, 1999
Status:	Prescription only
Route:	Intramuscular
Species:	Finned fish
Drug Form:	Powder (lyophilized)
Concentration:	10,000 I.U. per 10 mL when reconstituted
Indications:	As an aid in improving spawning.
Tolerance:	21CFR 556.304: Gonadotropin: No tolerance required. The ADI for residues of total gonadotropins (HCG and pregnant mare serum gonadotropin) is 42.25 I.U. per kilogram of body weight per day.
Withdrawal:	Zero days
Exclusivity:	3 years

21CFR 522.1081 and *556.304*

NADA Number: 141-095

This supplemental application provides for addition of a therapeutic claim for *Trichostrongylus axei* L4 and a persistency claim of 35 days for *Haemonchus placei*.

Trade Name:	Dectomax® Pour-On
Ingredients:	Doramectin
Sponsor:	Pfizer, Inc.
Approval Date:	August 10, 1999
Status:	Over-the-counter
Route:	Topical
Species:	Beef and non-lactating dairy cattle
Drug Form:	Liquid (solution)
Concentration:	5 mg per mL
Indications:	For the treatment and control of various roundworms, lung worms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites. Gastrointestinal roundworms: *Ostertagia ostertagi* (adults and L4, including inhibited larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and L4), *Trichostrongylus axei* (adults), *Trichostrongylus colubriformis* (adults and L4), *Cooperia oncophora* (adults and L4), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and L4), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and L4), *Trichuris* spp. (adults). Lungworms: *Dictyocaulus viviparus* (adults and L4). Eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults). Grubs: *Hypoderma bovis*, *Hypoderma lineatum.* Lice (biting): *Damalinia bovis* Lice (sucking): *Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus.* Mange mites: *Chorioptes bovis, Sarcoptes scabiei.* Horn flies: *Haematobia irritans.* The product has proved to effectively control infections and to protect cattle from re-infection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagi*, *Cooperia punctata*, and *Oesophagostomum radiatum* for 28 days after treatment.
Tolerance:	21CFR 556.225: Doramectin: A tolerance of 100 ppb is established for parent doramectin (marker residue) in liver (target tissue) and 30 ppb for parent doramectin in muscle. The ADI for total residues of doramectin is 0.75 micrograms per kilogram of body weight per day.
Withdrawal:	45 days
Patent Number:	5,089,480 Expiration Date: July 30, 2010
Exclusivity:	3 years

21CFR 524.770

NADA Number: 141-152

This supplemental application provides for the additional indication for control of tick infestations in dogs.

Trade Name:	Revolution™
Ingredients:	Selamectin
Sponsor:	Pfizer, Inc.
Approval Date:	August 5, 1999
Status:	Prescription only
Route:	Topical
Species:	Dogs and cats
Drug Form:	Solution
Concentration:	60 or 120 mg per mL
Indications:	For the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis* , and the treatment and control of ear mite (*Otodectes cynotis)* infestations in dogs and cats. Also for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*), for the control of tick infestations (*Dermacentor variabilis)* in dogs and for the treatment of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm infections (*Toxocara cati*) in cats.
Exclusivity:	3 years

21CFR 524.2098

ANADA Number: 200-146

This supplemental application provides for an additional package size of a 181.5 gram packet.

Trade Name:	Oxytetracycline HCl Soluble Powder
Pioneer:	008-622
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	July 26, 1999
Status:	Over-the-counter
Route:	Oral
Species:	Chickens, turkeys, cattle, swine, sheep
Drug Form:	Powder
Concentration:	55 mg per gram
Indications:	Chickens: For the control of infectious synovitis caused by *Mycoplasma synoviae*; chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*; and fowl cholera caused by *Pasteurella multocida*. Turkeys: For the control of hexamitiasis caused by *Hexamita meleagridis*; infectious synovitis caused by *Mycoplasma synoviae*; and in growing turkeys for the control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis). Swine: For the control and treatment of the following diseases: bacterial enteritis caused by *Escherichia coli* and *Salmonella cholerasuis* susceptible to oxytetracycline; bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: leptospirosis (reducing the incidence of abortions and shedding of *Leptospira*) caused by *Leptospira pomona* susceptible to oxytetracycline. Cattle:For the control and treatment of the following diseases in calves, beef cattle and non-lactating dairy cattle: bacterial enteritis caused by *Escherichia coli* susceptible to oxytetracycline; bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* susceptible tooxytetracycline. Sheep: For the control and treatment of the following diseases: bacterial enteritis caused by *Escherichia coli* susceptible to oxytetracycline; bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* susceptible to oxytetracycline.
Tolerance:	21CFR 556.500: Oxytetracycline: Acceptable daily intake (ADI). The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day. Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, beef calves, non-lactating dairy cattle, dairy calves, swine, sheep, chickens, and turkey at 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

21CFR 520.1660d

ANADA Number: 200-221

This supplemental application provides for the addition of tylosin tartrate as a local antibiotic for injection site infections.

Trade Name:	Component® TE-S with Tylan®
Ingredients:	Trenbolone acetate, estradiol, tylosin tartrate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	July 20, 1999
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle
Drug Form:	Implant
Concentration:	Each implant is made up of seven pellets. Six pellets each containing 20 mg trenbolone acetate and 4 mg estradiol, and one pellet containing 29 mg tylosin tartrate.
Indications:	For increased rate of weight gain and improved feed efficiency in feedlot steers.

ANADA Number: 200-221, con't

Tolerance: 21CFR 556.240: Estradiol and related esters: No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: In uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver.
21CFR 556.739: Trenbolone: A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed. The safe concentration for total trenbolone residues in uncooked edible tissues of cattle is 50 parts per billion (ppb) in muscle, 100 ppb in liver, 150 ppb in kidney, and 200 ppb in fat. A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animals. A safe concentration refers to the total residue concentration considered safe in edible tissues.
21CFR 556.740: Tylosin: Tolerances are established for residues of tylosin in edible products of cattle as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.

Exclusivity: 3 years

21CFR 522.2477

ANADA Number: 200-224

This supplemental application provides for the addition of tylosin tartrate as a local antibiotic for injection site infections.

Trade Names: 1) Component® T-S with Tylan®
2) Component® T-H with Tylan®

Ingredients: Trenbolone acetate, tylosin tartrate
Sponsor: Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date: July 20, 1999
Status: Over-the-counter
Route: Subcutaneous
Species: Cattle
Drug Form: Implant
Concentrations: 1) Each implant is made up of eight pellets. Seven pellets each containing 20 mg trenbolone acetate and one pellet containing 29 mg tylosin tartrate.
2) Each implant is made up of eleven pellets. Ten pellets each containing 20 mg trenbolone acetate and one pellet containing 29 mg tylosin tartrate.
Indications: 1) For improved feed efficiency in growing-finishing feedlot steers.
2) For increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers.
Tolerance: 21CFR 556.739: Trenbolone: A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed. The safe concentration for total trenbolone residues in uncooked edible tissues of cattle is 50 parts per billion (ppb) in muscle, 100 ppb in liver, 150 ppb in kidney, and 200 ppb in fat. A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animals. A safe concentration refers to the total residue concentration considered safe in edible tissues.
21CFR 556.740: Tylosin: Tolerances are established for residues of tylosin in edible products of cattle as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Exclusivity: 3 years

21CFR 522.2476

Change of Sponsor Name

From: Ivy Laboratories, Inc.
To: Ivy Laboratories, Division of Ivy Animal Health, Inc.
Drug labeler code: 021641